The New Biology and International Sharing - Lessons from the Life and Work of George P Smith II

Justice Kirby Collection

Date: 27 January 2000
Author: The Hon Justice Michael Kirby AC CMG Justice of the High Court of Australia
Type: Speech
Organisation: Indiana University, School of Law
Event: Inaugural Lecture of the George P Smith, II Distinguished Professorship-Chair of Law and Legal Research
Location: Bloomington, Indiana, United States of America

The Hon Justice Michael Kirby AC CMG [1]

PRESCIENT PROPHET OF THE NEW BIOLOGY **[2]**

R C O'Brien, "The World of Law, Science and Medicine According to George P Smith, II " 8 *Journal of Contemporary Health Law and Policy* 163 at 181 (1992) (hereafter "O'Brien").

Professor George Smith is a devoted *alumnus* of Indiana University. The University has conferred on him the degree of Doctor of Laws *honoris causa***[3]** . Now it has established a Chair of Law and Legal Research which bears his name. I have come from the other side of the world to give this lecture helping to inaugurate the new chair.

I have done so because of two decades of friendship for Professor Smith and respect for his "truly awesome" writings**[4]** . But I have also taken this long journey to make it clear that this native of Wabash and graduate of this University is honoured far away as well as close to home. He is, as Balfour said of Joseph Chamberlain, "No man of the hour. He is a man of tomorrow and the day after tomorrow"**[5]** . As his students at the Catholic University of America wrote in the *Journal of Contemporary Health Law and Policy,* which he established and in a volume dedicated to his name, he exhibits an "indefatigable spirit and sense of total commitment"**[6]** to "high standards of professionalism and unstinting devotion to his students"**[7]** . This University, honouring him with the Distinguished Alumni Award as long ago as 1985 extolled his prodigious energy and uncompromising principles; "his inquisitive mind [which] is constantly searching to expand his horizons and those of the legal community" by "his unstinting labours"**[8]** .

George Smith's fellow citizens in Indiana have done well to celebrate the work of this remarkable law teacher and scholar. Astonishingly enough, he has maintained his prodigious output since the days of his youth. And there is no hint of a decline in his energy. One colleague, who would know, commented that a day in his life was not the same if he did not write three thousand words in final form**[9]** . On a good day (ie one that is cloudy, overcast or raining) he has been known to write as many as eight thousand words. What irritates mere mortals of hesitant-tied disposition is the amazing way in which George Smith combines the highest of scholarly rigour with deliberate intellectual provocation, the exploration of dark corners of present and possible future scientific developments and the quest for solutions in

The New Biology and International Sharing - Lessons from the Life and Work of George P Smith II

Justice Kirby Collection

the law that will be necessary if we are to cope adequately with the dilemmas of contemporary science and technology**10** .

It is now well established that, in recent years, there has been a falling off in published essays and speeches by United States judges. There are some exceptions. Chief Judge Richard Posner for example (whose output gives even Professor Smith a challenge) seems partly intent upon single-handedly filling the void occasioned by the reticence of others**11** . The usual explanation for this general statistic is the concern felt by some, with an eye on a Supreme Court vacancy, arising from the political analysis of the extra-judicial writings of Judge Bork leading to the rejection of his nomination to the highest court**12** . In my view, the real explanation is that few judges could rival the engaging titles chosen by contemporary academics for their law review contributions.

Fewer still could challenge George Smith in this connection. The titles of his essays are obviously designed to capture attention and to challenge the reader to read further. A few illustrations will be sufficient to make this point good. Take, for example, the following titles: "Stop, in the Name of Love!"**13** ; "From Cutlass to Cat-O-Nine Tails"**14** ; "Patient Dumping: Implications for the Elderly"**15** ; "Reviving the Swan, Extending the Curse of Methuselah"**16** ; "Murder She Wrote, Or Was it Merely Selective Non-Treatment?"**17** ; "Alls Well That Ends Well: Toward a Policy of Assisted Rational Suicide"**18** ; "Lost Horizons, Captains Courageous and Disabled Newborns"**19** ; "Intimations of Immortality"**20** ; "The Ice Person Cometh: Cryonics and the Law"**21** ; "The Razor's Edge of Human Bonding"**22** ; "For Unto us a Child is Born - Legally"**23** ; and "Through a Test Tube Darkly"**24** . There are dozens more. They display the author's love of literature and poetry and his utter rejection of quiet orthodoxy and temperate under-statement. Readers know from the headline that this is, as his students have averred, a dramatic communicator**25** who rejects the studied understatement of most disciples of the law. Whereas he has learned lessons from the banners of the tabloids, the content of his writings into which we are so provocatively drawn is rigorous and scholarly. Yet it never forsakes readability or the challenge to a lively intellect.

A review of the legal writings of George Smith over thirty years bears witness to several recurring themes - many of them on black letter topics that would gladden the hearts of the most conservative of jurists. For example, one of his monographs is on environmental control in Arkansas**26** . Environmental law, land use and associated legal themes of nuisance law make up a scholarly collection. So do his essays on the law of remedies, with their examination of the mollifying impact of equity upon the common law which you in the United States and we in Australia derive from the legal traditions of England's Chancery court. He has written much on property law**27** , and not a little on civil liberties, sexuality and jurisprudence.

However, it is in the field of health law, and in the special realm of bioethics and the law, that George Smith has become a world-recognised scholar of the first rank. He is much in demand as a Visiting Fellow at universities everywhere. This demand has taken him not only

to the great universities of his own country but also to their counterparts in England, Germany, Italy, Scandinavia, the Netherlands and my own country, Australia.

We first met in 1982 when he lectured for the first time at the University of New South Wales in Sydney, Australia. He has since returned there on many occasions. At the time I was the inaugural chairman of the Australian Law Reform Commission. That Commission had then recently concluded a report on human tissue transplantation**28** . Professor Smith's own growing interest in the law and bioethics and my new-found acquaintance with its mysteries, brought us together. Since then, we have met on every occasion that he has returned to Australia. I have watched with fascination and admiration his remarkable career and virtually unequalled output. He did not choose a safe area of the law whose perimeters were chartered in the *Year Books* and whose dilemmas had been worked over for centuries. Instead, his inquisitive mind took him into the most puzzling interface of law and modern technology. He simply could not let the topics alone. He cogitated and analysed and lectured and wrote. All the time, the scientific and technological foundation for his studies was shifting dramatically.

Professor Smith's first entry into law reform occurred as long ago at 1969. In that year he served as a consultant to the New York Assembly (as he did later the Pennsylvania State legislature in 1976). They developed model legislative drafting proposals concerned with a then big issue of law and bioethics - artificial insemination donor**29** . Just to mention that topic indicates the dynamics of scientific and technological developments that have accompanied Professor Smith in his journey through bioethics and the law. Artificial insemination husband (AIH) had given way to artificial insemination donor (AID). The law reviews were full of the exploration of these themes. Soon they were overtaken by human tissue transplants (HTS). And then this was displaced by *in vitro* fertilisation (IVF). Soon this too was replaced by new dilemmas of artificial reproduction. Now we have seen the creation, by reproductive cloning, of the sheep Dolly**30** . Today, it seems, we are on the brink of reproductive cloning of the human species**31** .

In the space of the years of our friendship - fewer than 20 years - the technological revolution in biology and genomics has presented problems of ever greater magnitude and at a seemingly unstoppable pace in both number and difficulty. How easy it would be to surrender to the pageant of truly difficult dilemmas for ethics and the law which it presents. Most mere mortals would do so. If a law professor or a judge, they would turn their attention to simpler and safer fields - such as taxation legislation or (if they were venturesome) the law of restitution. But George Smith responded with an energy atypical of the law and more typical of the scientific imagination which was presenting the problems in the first place. He has kept pace with the most puzzling challenges of our time. Not content with this, he has looked searchingly into the future for other difficult problems that are just around the corner - such as the challenge to from acid rain**32** and the potentiality of cryonics to give Elizabeth Taylor (and eventually the rest of us) the hope of palpable immortality**33** . For those who

laugh at these issues and call them science fiction, not science, it is necessary to reflect upon all that has happened in the past decades. Scientific achievement often grows out of scientific imagination. Someone in the law should be keeping pace. More often than not, that someone is George Smith.

With thanks for his many contributions to legal scholarship and law teaching in Australia and in acknowledgment of his extraordinary work over such a sustained period, I have come to the place of his origins to help inaugurate the Chair of Law and Legal Research which is named for him. I am proud to have that honour. It will be a daunting chair for its incumbents. A minimum of 8,000 words a day will be expected. And they will need to be addressed to cutting edge issues, not to the safe backwaters of the law.

SEARCHING FOR A PRINCIPLE

It is one thing to recognise the dilemmas of bioethics and law and another to contribute in scholarly and practical ways to elucidating the choices that must be made. The methodology of the common law encourages a mode of thinking which responds to each practical problem as it arises. This pragmatic methodology encourages the decision-maker to move from precedent to precedent, as Tennyson said, applying a past decision by analogous reasoning when confronted by a new dilemma.

The difficulty with this methodology is nowhere more evident than in the field of bioethics. Here, lawyers, and other policy makers, are confronted by a number of acute and special problems. The lay observer will not always understand, or understand fully, the scientific development which has occurred and the technological applications that have sprung from that development. Looking back on the century which is about to close we can perceive at least main three scientific advances which have changed the face of our planet. They are nuclear fission; informatics; and biogenetics. Somewhere, awaiting discovery, is a grand theory which will explain the interconnections of all of these scientific discoveries. It is easy enough to conceive the connections between informatics and genetics. Unravelling the secrets of the human genome would be impossible without the assistance of computers to perform the essential analysis of the data. But as that data is presented and takes the scientist and the technologist into even more dramatic developments, the lawyer and the ethicist tend to be left behind. For the most part, like the layman, they cannot really comprehend the detail of science, still less where it is leading. They cannot keep up with the pace of change. They cannot foresee the leaps of scientific imagination that occur in a propulsion of ideas, not by linear development. Above all, they lack a general methodology which will offer a consistent approach to the way in which the law should respond to such new dilemmas.

Some urge resort to religious dogma. But so extraordinarily varied are the puzzles that we must now confront that dogma is often unhelpful to the specificities of contemporary problems. Professor Smith, himself a religious man, writes**34** :

The New Biology and International Sharing - Lessons from the Life and Work of George P Smith II

Justice Kirby Collection

"If the Church is largely ignored today it is not because science has finally won its age-old battle with religion, but because it has so radically re-oriented our society that the biblical perspective of the world now seems largely irrelevant. As one television cynic recently remarked, few of our neighbours possess an ox or an ass for us to covert. The deep questions of existence are approached differently by science and religion. While science is based on both careful observation and experimentation which in turn allow for theories to be constructed connecting different experiences, religion asserts unalterable truths which cannot be modified to accommodate changing ideas. Accordingly, the true believer stands by his faith regardless of whether evidence may be deduced against its efficacy. Yet for the scientist, if scientific irregularities prove a theory to be fallacious, it will be abandoned and a new approach adopted".

This conclusion leads George Smith to the opinion that traditional religions "often appear to be lacking in modern relevance in resolving both personal and social problems"**35** . Unless the law is to turn a blind eye and have nothing to say to science, it is essential that tools must be found to provide just, efficient and realistic solutions to the many new problems that we must confront and solve. Nobody would pretend to a total theory which will provide a universal solution to such problems. The old common law found comfort in notions of fairness or reasonableness. Economic rationalists will insist upon maximising economic freedom. Philosophers may search for ideas inherent in our very humaneness. But even this will be inadequate as the Human Genome Project presents our species with the potential to redefine humaneness and to alter the genetic makeup of future human beings.

Searching for his own solution, Professor Smith has suggested that a basic idea which may help us to answer the dilemmas of bioethics is the force of human love. He regards this as the driving force of the conscious life of the human being which makes the individual, in the words of Dr Joseph Fletcher of the University of Virginia "grow in love of God and neighbour"**36** . This is how George Smith expresses his fundamental principle**37** :

"Since the binding force of life is love, then it can be argued that [humans] should endeavour to maximise a response to love in whatever situations [a human] finds himself. If an act renders more harm than good to the individual concerned, and to those around him, the act would properly be reviewed as unloving. The crucial point of understanding is that a basic cost/benefit analysis is almost always undertaken - consciously or unconsciously. Of course the methodology utilised in this assessment would be situational and incapable of absolute determination. Of necessity, the basic norm or standard to be used will be love".

These words resonate with the thirteenth chapter of St Paul's first letter to the Corinthians. In words so familiar to people of all religions, and of no religion, the writer of that letter explains the dilemmas which bioethicist, lawyer and philosopher must face and how none of us is excused from the obligation to face them**38** :

The New Biology and International Sharing - Lessons from the Life and Work of George P Smith II

Justice Kirby Collection

"Love never faileth: but whether there be prophecies, they shall fail; whether there be tongues, they shall cease; whether there be knowledge, it shall vanish away.

For we know in part, and we prophesy in part.

But when that which is perfect is come, then that which is in part shall be done away.

When I was a child, I spake as a child, I understood as a child, I thought as a child: but when I became a man I put away childish things.

For now I see through a glass, darkly; but then face to face: now I know in part; but then shall I know even as also I am known.

And now abideth faith, hope and love, these three; but the greatest of these is love".

In an age when there is so much pressure to solve problems by reference solely to economic criteria (and selfish ones at that) it is surely important to have voices which suggest that difficult quandaries can be solved by reaching into our capacity for love and respect for other human beings and other species. Those we love may include human beings outside our nuclear family: those whom we do not even know. Those whom we know and do not fully understand. Respect for fundamental human rights and human dignity is one of the key movements which has grown out of the catastrophic disasters of the twentieth century. On an otherwise dark landscape, the achievements in the field of human rights represent bright beacons of hope as we enter a new century. Despite some critics (many of them autocrats) who doubt the universality of human rights and urge a multitude of cultural exceptions, it is important to recognise that it is the overwhelming genetic commonality of the human species that stamps upon the discourse of human rights its search for universal principles. Like Professor Smith, I have always thought that the foundational idea behind respect for the human rights of family and strangers, indeed of every other member of our species and beyond, is a love which we feel in potential for them as creatures whose lives are overwhelmingly similar to or shared with our own.

To bring these generalities to an element of specificity, I wish to turn to two highly practical and somewhat urgent dilemmas of a bioethical character. Each of them has, in potential, legal implications. Each of them illustrates the inadequacy of economics as a universal principle to provide the solutions. In a highly diverse world of international problems, each illustrates the impossibility of offering solutions by reference to the dogmas of particular religions. In a world of diverse religions, and of no religion at all, it is increasingly impossible to impose on the whole world solutions which reflect the values and beliefs of one religious tradition alone. Each also illustrates the dilemma of sharing. How do we share the benefits and burdens of important technological advances potentially affecting the health and well-being of our species. What are the principles of distributive justice which will help us to find the solutions for the laws and policies which we should adopt?

The New Biology and International Sharing - Lessons from the Life and Work of George P Smith II

Justice Kirby Collection

THE DILEMMA OF HIV VACCINES

The fastest spreading new pathogen, threatening life in the human species today, is the Human Immunodeficiency Virus ("HIV") which ordinarily progresses to Acquired Immuno Deficiency Syndrome ("AIDS")**39** . In the absence of readily available therapeutic drugs or effective vaccines, the only remedy accessible to most societies is behaviour modification. As any lawyer can tell, from millennia of experience of the law, changing the behaviour of people in conduct (including sexual and drug use) which is pleasurable and important to identity, is most imperfect. If it occurs at all, it is extremely slow and intermittent. For any degree of effectiveness, it is necessary, in the case of HIV, to challenge entrenched religious, moral, social and other sources of resistance. Nevertheless, because it is estimated that every day 16,000 new HIV infections occur, there is enormous pressure, particularly in developing countries devastated by the virus, to secure an effective vaccine. This is said to be, in most developing countries, the only "realistic" way to deal with the epidemic**40** . It is why in recent years there has been a renewed commitment of government leaders, including in the United States, for the development of HIV vaccines**41** . One health minister from a developing nation afflicted by the epidemic observed: "If you don't get on with this soon there will be no one left to test"**42** . Even a low efficacy limited impact vaccine in places of major spread of HIV, protecting some of the individuals at primary risk to spread of the virus would, on mathematical population models, have a huge impact on the spread of HIV**43** .

It is exactly 200 years since Edward Jenner released his study on the first vaccine known to humanity, that against smallpox**44** . One by one, other conditions have responded to immunisation: yellow fever, plague, polio, diphtheria, tetanus, typhoid, whooping cough, rabies and measles. Most of these conditions are produced by bacteria (such as typhoid) or by a comparatively stable virus (such as smallpox). HIV/AIDS presents particular challenges to vaccine development. Such challenges stem from the mutations of HIV, the multiple strains in which the virus manifests itself and the social context in which those affected have to live and work.

George Smith's principle of love requires us to face squarely this bioethical dilemma. It necessitates recognition of the fact that *not* to act is often to make an ethical decision. Not to invest in HIV vaccines but to do so in genetic cures for wrinkles because that would be more profitable is to make an ethical choice. Not to press on with trials for fear of the legal risks which they may involve is to make such a choice. To conduct the trials only in developing countries may seem a sensible course because of political pressure there, strong governmental support, the ease of securing local participants and the unlikelihood of legal proceedings if things were to go wrong. But it involves an ethical election.

Trials of HIV vaccines in the United States have been discontinued because, everyone knows that legal liability for mishaps would be scrupulously enforced in the courts**45** . Yet the shift of trials to developing countries where such risks are minimal presents new problems**46** . These arise, in part, from the fact that the market for HIV vaccines that would render the

investment profitable is largely in the developed world where the strains of the virus may be different. Furthermore, there is an increasing recognition that the conduct of such trials in developing countries must be on the basis that the people who take part in them, and the nations which facilitate them, must reap a just return ("the vaccine dividend") if the trial goes ahead and later a commercially viable vaccine emerges as a result.

Three principles should govern the conduct of prophylactic or therapeutic research into HIV involving human beings. Those principles are, first, respect for the persons involved, their autonomy in decision-making and self-determination. Secondly, beneficence: maximising benefits and minimising harms to such persons. And thirdly, distributive justice, that is equitable distribution of both the burdens and benefits of participation in research**47** . In common law countries we are quite familiar with the first two principles. We protect the individual. We insist upon beneficence. We do so in the decisions of the courts which demand that patient consent be truly informed and that the only justification for medical intervention (which would otherwise be an assault or trespass to the person) is the purpose of those involved to secure the best interests of the patient**48** .

It is the principle of distributive justice which makes the ethical decisions in a field such as the development of HIV vaccines somewhat different from the ordinary ethical choices which the law enforces. In this dilemma, the ultimate question is: what is in it for the people of Uganda or Thailand who are submitted to a HIV vaccine trial which we do not conduct upon people in the developed world whose pharmaceutical companies have developed the vaccine? What can, and should law and policy makers in developed countries do to address the issues of distributive justice which the trialling of HIV vaccines necessarily raises?

Past experience with the conduct of trials for medical purposes teach the need for great vigilance. The Tuskagee study in the United States denied newly developed penicillin to indigenous victims of syphilis even after that drug was widely available throughout the country**49** . Subsequent revelations also showed how human subjects were radiated without being aware of that fact or of the dangerous risks to which they were being exposed**50** . In the case of HIV, there is a possibility (I put it no higher) that, because of its high volatility, the virus may "unattenuate". An attenuated strain involving dead virus might come back to life to threaten a person vaccinated with it**51** . Although, in accordance with standard procedures, clinical trials on animal subjects have first to be exhausted**52** , the point is reached when it becomes scientifically essential to conduct a clinical trial on human subjects. That is the point at which measured risks must be taken. They have to be taken with a clear appreciation of the urgency which faces humanity. But it is also necessary to ensure that there is a sharing of benefits and burdens. In short, people in far-away developing countries should not be reduced to the status of objects. It is the ethical, and should be the legal, duty of individuals and corporations in developed countries to make sure that scientists and entrepreneurs proceed in a way that respects the basic human rights and human dignity of the trial group and the communities in which such trials take place.

The New Biology and International Sharing - Lessons from the Life and Work of George P Smith II

Justice Kirby Collection

Ethical principles require that those who participate in a HIV vaccine trial must be alerted, counselled and reinforced in the lessons of behaviour modification. At the moment, this represents the only certain means of preventing sero-conversion. Trial subjects must not put their faith in the vaccine with which they are being tested. Whether they receive the experimental product or a placebo, they must be constantly reminded about self-protection. Yet paradoxically, the effectiveness of any HIV trial will only be proved if some of the participants do not receive, or ignore, such messages and become infected**53** . In this sense, those involved in HIV vaccine trials have, potentially, an operational interest in the sero-conversion of some of those receiving the placebo. They also have an operational interest in the exposure to risk of those who receive the vaccine product. I do not, of course, suggest a *desire* that others become infected or a cold indifference to that possibility. I do not more than call to notice the operational necessities of any drug or vaccine trial.

In non-life threatening vaccine trials (mumps, measles and so on)**54** such potential conflicts of interest and duty may be tolerable. Where HIV/AIDS is concerned, they require the highest possible vigilance and strict scrutiny of the trial. The World Bank and international initiatives of the United Nations inter-agency, UNAIDS, are addressing the foregoing dilemmas which are truly global in character. Because HIV is a virus of the human species and because it spreads rapidly by a movement of people to every part of the world, very few communities are completely immune from its devastation. In providing a response, it is not enough for the law to attempt to impose barriers at the frontier. They will not work. Law, to be ethical, should support vaccine trials and the international efforts to conduct them. Yet if such trials are to take place, potentially for the benefit of people in other lands, distributive justice suggests the need to protect those who take part, to defend them if the trial fails and to reward them if the trial produces a commercially viable vaccine.

These principles can be stated in general terms. George Smith would doubtless explain that they have their ultimate foundation in the love and respect which we should share for every creature who partakes of the humanity which is also our own. Legal regulation should not be so onerous as to discourage still further the investment in vaccine development, trials and marketing that are essential to any effective and global scientific response to the AIDS epidemic. Yet distributive justice obliges that attention should be given to those submitted to trials in other lands. If, ultimately, there are successful HIV vaccines they will represent a commercial bonanza. In that event, what is the reward that will be shared with those whose risk-taking made it possible? Has the law a role to ensure that they benefit directly for their contribution?

THE GENOME AND BENEFIT SHARING

The Human Genome Project is the largest cooperative scientific enterprise in history. It involves the mapping of the human genome comprising approximately 100,000 genes that determine the genetic makeup of each human being. The project, which is ahead of schedule, is expected to be completed in the year 2003. Even when the location of the genes

in the structure of the human DNA is known, the function of most of them will, for the time being, remain unknown**55** . Scientists will have a great mass of data. It has been likened to "a very large encyclopaedia written in an unknown language"**56** . But the hope is that the functions of all of the genes will eventually provide knowledge that will help medical science to treat more than 4,000 genetic diseases which presently afflict humanity as well as many other diseases in which genetic predisposition plays an important role.

It is not my present purpose to identify even the main ethical and legal quandaries which the Human Genome Project presents**57** . The UNESCO *Universal Declaration on Human Rights and the Human Genome***58** bases its approach upon the requirement to defend human dignity and the common heritage of humanity. These objectives are sometimes explained by reference to Immanual Kant's second formulation of the categorical imperative**59** . This instructs that one should "act in such a way that you always treat humanity, whether in your own person or in the person of any other, never simply as a means but always at the same time as an end".

Mutations or variations in the human genome may be important to the discovery of therapies that will be developed from the scientific research. They may result in drugs potentially of high profitability. Take two examples, not wholly theoretical:

- Research on prostate enlargement has led to a study of particular families, many of them in developing countries, which have manifested an apparent immunity resulting in the natural development of an inhibitor against prostate enlargement. If the development of the steroid appearing in this group of human beings could be isolated, it could ultimately be of great benefit in the treatment of prostate enlargement in the general population of many countries. This is a common human ailment. If pharmaceutical companies, seeking to protect large investments in the research and development that may produce medications for such treatment seek the protection of patents over their discovery, should such protection be available to them? If so, for how long? Should rewards be paid, in the event that a medication results in large profits to the pharmaceutical company? If so, to whom should the rewards be paid? To the individual from whose genetic particularity the treatment was refined? At least in developing countries, to the village of such donors or to their tribe or social group? Or to their nation so that it can be ploughed back into medical treatment of others both for prostate enlargement and for other conditions**60**

- Researchers from a developed country, studying the genetics of nicotine dependence take samples from patients in an isolated village in China. As a condition for the award of a research grant, they bank their samples permanently. They make them available, on request, without charge to other researchers, including commercial entities. They do not provide the names of the individual donors. The researchers find several promising genetic markers for nicotine dependence in the samples. Later a

> pharmaceutical company using the samples discovers a gene associated with these markers. After many years of research and development, the company produces an immensely profitable drug to combat nicotine addiction in the human species. Does the company owe anything in these circumstances to the original donors in China if they could be found? To the original researchers? To the village or ethnic group of the donors? To China as a country? Does any principle of benefit sharing require the provision of benefits to these individuals, groups or nations? If so, is it provided for reasons of justice? Or possibly for reasons of prudence to avoid political, economic or other opposition? Or as charity, out of the pocket of the rich into the pocket of the poor**61**

These are the questions which are being examined by the Ethics Committee of the Human Genome Organisation. The answers that are given will not be found in the teachings of any particular religion. These questions are addressed to the whole world with its multitude of religions, philosophies and beliefs. The answers will draw upon the international guidelines which have been developed by the World Health Organisation**62** and other bodies. As in all bioethical reflections, it is necessary to approach the quandaries from a thorough understanding of the practical environment in which they arise.

Some human diseases such as river blindness and sleeping sickness appear virtually exclusively in poor developing countries. WHO estimates that more than $56 billion is spent globally each year on health research. However, less than 10% of that sum concerns diseases which afflict 90% of the world's population. Multi-national pharmaceutical corporations do not ordinarily invest in new products unless they offer the promise of large and preferably prompt returns. "Turning a glean in the researcher's eye into a handful of useful pills is an expensive and time-consuming business: on average it costs $300 million and takes more than a decade. Between 1975 and 1997 an impressive 1,223 new [medical] compounds were launched on the market. But only 11 of them were designed for tropical diseases"**63** .

Already, particular national groups have begun to negotiate arrangements by which there is a trade-off between the group participating in a genetic trial and the pharmaceutical company conducting it. In February 1998, Hoffman-La Roche, Switzerland, agreed to an arrangement for a contribution to the government of Iceland of $200 million over five years. During that time, the company will study the genes and alleles (or mutations) that predispose Icelandic people to the development of up to twelve common diseases. These diseases include four cardiovascular diseases, four psychiatric-neurologic diseases and four metabolic diseases. The project is called "deCode". It has been described by its supporters as "the first example of recognition of the patient population contribution to the drug discovery by a pharmaceutical company". Under deCode Icelanders "will receive medications developed for their contribution free of charge".

Although there has been some opposition within Iceland and elsewhere to the scheme, the project has been fully developed in the Icelandic community and decided in the democratically elected Parliament of Iceland. Decisions have been made by the community through its legislature to accept the bargain with the pharmaceutical company. Its supporters present deCode as a modern example of benefit sharing**64** . There are similar developments in other countries. However, for the most part, developing countries and the governments, tribes, villages and individuals in them who participate in such trials are less well positioned than the representatives and people of Iceland are to insist that they should share the benefit of research and gain the "genomic dividend" if the study of their mutations produces therapeutic or prophylactic medicines which are of benefit of human health and profitable to the companies that market them.

In a partial response to these developments, the World Bank and WHO, together with a number of donor countries and philanthropic organisations, have formed the Global Alliance for Vaccines and Immunisation. The object of this body is to improve access to existing vaccines in developing countries and to support the development of new vaccines**65** . The programme envisages "contingent lending" by which donors in developed countries will afford capital on the basis that needy countries will agree to purchase the vaccine if and when a useful one appears. Since December 1998, the Gates Foundation has provided $50 million for malaria vaccine development, $25 million for HIV/AIDS vaccine research and $100 million for global children's vaccine programmes. The last aims to improve access to expensive new vaccines against hepatitis B and the influenza virus. International developments of this kind, both within global institutions and by private bodies, assist in sharing the benefits of international medical research, including that derived from the Human Genome Project**66** . The law is not irrelevant to these developments. The reform of intellectual property law (patents and copyright) and the enactment of legislation which ensures that domestic corporations, subject to local law, conform to basic norms of individual and distributive justice represent ways by which George Smith's principle of love for fellow human beings, wherever they are, may be reflected in the ethical decisions to which such laws give effect.

CONCLUSIONS

George Smith has frequently made the point that, at least in common law countries, there is always a potential legal decision-maker who will solve dilemmas and provide binding norms. Where a problem is presented which involves serious disagreement, there is never a legal gap. Even if the legislative and executive branches of government fail or run away from such dilemmas, this is not a privilege open to judges in a properly constituted suit. They must find a solution, even if this involves making new law by analogical reasoning from past judicial decisions. In a recent essay, Professor Smith quotes Professor Roger Dworkin to explain the limitations inherent in judge-made solutions**67** :

The New Biology and International Sharing - Lessons from the Life and Work of George P Smith II

"Common law judges have no power to issue advisory opinions or proffer generalised codes of conduct. They have no power to rule for the future even about problems that seem certain to arise. This means that for the common law to deal with technology the technology must exist and have operated in a way that angered someone enough for that person to have claimed injury and sought legal redress. Thus, to the extent that a rapid response or response in advance of a bio-social development is important, the common law cannot provide it. Common law is reactive, not proactive".

Dilemmas of bioethics can sometimes elicit solutions to complex problems from distracted and nervous lawmakers. In 1997, President Clinton banned the use of federal funds for human cloning**68** . Subsequently he settled on a five year moratorium**69** . Later still, the National Bioethics Advisory Commission of the United States recommended federal legislation be enacted to allow a limited number of scientists to create cloned human embryos for a limited time for further scientific research aimed to benefit humanity. The Commission suggested that the use of such embryos for human reproduction be prohibited**70** .

Ultimately, one could imagine cases coming before the courts in which many of the dilemmas presented by genetic and genomic science have to be solved. An individual or group affected in a foreign country may sue a local corporation for breach of proper standards in the conduct of a HIV trial. Individuals concerned may seek redress for the use without authority of their genetic materials in the development of a therapy or vaccine. Claims to distributive justice, as well as individual entitlements, may come to engage the judiciary in the future. Certainly, they will require the attention, and properly so, of the legislature and the executive branch. When this occurs, it will be important for decision-makers to have guidance from those who have thought deeply about these issues, identified the scope and nature of the questions and explored some of the answers. When this happens, it is certain that the writing of Professor Smith, as a "prescient prophet of the new biology"**71** , will be in the forefront of the thinking of the decision-maker.

George Smith holds up the light of his scholarship to the rest of us. He sheds light into dark and mysterious places, where the darkness threatens to encircle us and the mysteries deepen and multiply into a gloom**72** . For this we must be grateful. To say so, I have crossed the world to express the gratitude of many outside the United States. Professor Smith should continue to cajole, stimulate, irritate and aggravate us. He should continue to seize our attention and to present us with the great puzzles of our time. Given the changes that have come about in the thirty years of scholarship and the acceleration of change which we have witnessed, we will need him and others like him to apply human intelligence to great issues as we enter a new century where the dilemmas will only become more difficult.

Can our democratic lawmaking institutions survive these challenges? Or will our institutions remain as often irrelevant relics of an earlier, simper age? That is the fundamental question which bioethics presents to the law. Professor George Smith, son of Indiana University, is not

content to walk away from such problems. He shows the obligation, and the means, to respond. But will we have the imagination and the courage to follow?

1 Justice of the High Court of Australia. One-time Chairman of the Australian Law Reform Commission and member of the WHO Global Commission on AIDS. Member of the International Bioethics Committee of UNESCO. Member of the Ethics Committee of the Human Genome Organisation.

2 R C O'Brien, "The World of Law, Science and Medicine According to George P Smith, II" 8 *Journal of Contemporary Health Law and Policy* 163 at 181 (1992) (hereafter "O Brien").

3 Conferred 9 May 1998.

4 O'Brien, 182.

5 Dedication to Professor Smith, 2 *Journal of Contemporary Health Law and Policy* 1 (1986).

6 *Ibid,* 1 .

7 *Loc cit.*

8 *Ibid,* 2.

9 O'Brien, 165.

10 O'Brien, 181.

11 See eg R Posner, *An Affair or State,* 1999 reviewed *ABA Journal* , November 1999, 98.

12 S Gaille, "Publishing by US Court of Appeals Judges: Before and After the Bork Hearings" 26 *J Legal Studies* 371 (1997).

13 19 *Anglo-American Law Review,* 55 (1990).

14 10 *Michigan Journal of International Law* 277 (1989).

15 6 *Elder LJ* 165 (1998).

16 2 *Cambridge Quarterly Healthcare Ethics* 49 (1993).

17 8 *Journal of Contemporary Health Law and Policy* 49 (1992).

18 22 *University of California-Davis Law Rev* 275 (1989).

19 1 *Reports Seventh World Congress on Medical Law* 75 (1985).

20 (1983) 6 *Uni of NSW LJ* 119.

21 1 *Journal of Comparative Health Issues* 23 (1983).

22 5 *Western New England L Rev* 639 (1983).

23 56 *American Bar Association J* 43 (1970).

24 67 *Michigan L Rev* 127 (1968).

25 2 *Journal of Contemporary Health Law and Policy* 1 (1986). A bibliography of the writings of Professor Smith from 1964-1989 may be found at 6 *J Contemp Health L & Pol'y* 483-

493 (1990).

26 (1970).

27 Paper, The Right to Property Law in American Constitutional Law, Konrad Adenauer Foundation, Conference on German and American Constitutional Law, Notre Dame University, April, 1986. See also G P Smith & Griffin W Fernandez, The Price of Beauty: An Economic Approach to Aesthetic Nuisance, 15 *Harv J Envt'l Law* 53 (1991); G P Smith, Nuisance Law: The Morphogenesis of an Historical Revisionist Theory of Economic Jurisprudence, 74 *Neb L Rev* 658 (1995).

28 Australian Law Reform Commission, *Human Tissue Transplants* (ALRC 7, 1976), AGPS, Canberra.

29 O'Brien, 181-182, fn 132.

30 G P Smith, "Judicial Decisionmaking in the Age of Biotechnology" 13 *Notre Dame J of Law, Ethics & Public Policy* 93 at 112-116 (1999).

31 *Ibid,* 114-115. cf R Brownsword (ed), *Law and Human Genetics: Regulating a Revolution* (Oxford, 1999).

32 G P Smith, "Acid Rain: A Transnational Perspective" 4 *NYLS J International and Comparative Law* 459 (1983).

33 "Intimations of Immortality: Clones, Cryons and the Law" (1983) 6 *UNSWLJ* 119.

34 G P Smith, *Judicial Decisionmaking,* above n 29, at 100.

35 *Loc cit.*

36 G P Smith, "Quality of Life, Sanctity of Creation: Palliative or Apotheosis?" 63 *Neb L Rev* 709 at 732 (1984) (citing R A McCormick, *How Brave a New World? Dilemmas in Bioethics* , 349 (1981)). See O'Brien, 177-178.

37 *Loc cit.*

38 1 Cor 13, 8-13.

39 *AIDS Policy and Law,* 30 September 1994 (Vol 9 No 18), 1, 8.

40 Dr W Paul (Director, Office of AIDS Research, NIH) quoted *AIDS Policy and Law* 30 September 1994, 1.

41 United Kingdom, *National AIDS Manual,* AIDS Research Manual (ed K Alcorn, 1998-1999), 280.

42 Quoted C Grady, "HIV Preventive Vaccine Research: Selected Ethical Issues" 19 *Journal of Medicine and Philosophy* 596 at 598 (1994).

43 *National AIDS Manual* above n 40 at 284.

44 E Jenner, *An Inquiry into the Causes and Effects of the Variolea Vaccinae* (1798).

45 US Code of Federal Regulations 45 CFR 46.116(4) ["the subject must be 'informed of appropriate alternative procedures or course of treatment if any that may be

advantageous to the subject'"] and 45 CFR 46.111(2): ["the risks to subjects [must be] reasonable in relation to the anticipated benefits, if any, to subjects and the importance of the knowledge that may reasonably be expected to result"]. See C Grady, above n 41, at 607.

46 U Schûklenk, "The Ethics of Clinical AIDS Vaccine Trials in Developing Countries - A Critical Commentary" (1994) 13 *Monash Bioethics Review* 13. The author criticises the views of N Christakis, "The Ethical Design of an AIDS Vaccine Trial in Africa" 18(3) *Hastings Center Report* 31 (1988).

47 J Thomas, "Ethical Challenges of HIV Clinical Trials in Developing Countries" (1998) 12 *Bioethics* 320 at 322.

48 B N Dickens, "Legal Approaches to Healthcare Ethics and the Four Principles" in R Gillon (ed) *Principles of Healthcare Ethics* 1994 305 at 308 referring to *Kruzan v Director, Missouri Department of Health* 110 SCt 2841 (1990); *Sidaway v Bethlem Royal Hospital* [1985] 1 AC 871. See also *Schloendorff v Society of New York Hospitals* 211 NY 125(1914); *Canterbury v Spence* 464F 2d (1972).

49 D B Resnik, "The Ethics of HIV Research and Developing Nations" (1998) 12 *Bioethics* 286 at 301ff.

50 *Ibid,* 306.

51 *The Economist,* 4 July 1998.

52 C Grady, "HIV Preventive Vaccine Research: Selected Ethical Issues" 19 *J Medicine and Philosophy* 596 at 598 (1994).

53 S Kippax and J Crawford, "Prophylactic Vaccine Trials: What is Different About HIV?" (1995) 8 *Venereology* 178 at 179.

54 C Grady, above n 51, at 598-608.

55 L Rowen, G Mahairas and L Hood, "Sequencing the Human Genome" (1997) 278 *Science* 605; G Schuler et al, "A Gene Map of the Human Genome" (1996) 274 *Science* 540. See also J Kinderlerer and D Longley, "Human Genetics: The New Panacia?" (1998) 16 *Modern Law Review* 603.

56 J Kinderlerer and D Longley, above n 55, at 604.

57 See Brownsword, above n 30. cf G P Smith, Harnessing the Human Genome Through Legislative Constraint, 5 *European J Health L* 53 (1998); G P Smith, Genetic Determinism or Genetic Discrimination? , 11 *J Contemp Health L & Pol'y* (1996).

58 Adopted, Paris,11 November 1997.

59 Immanuel Kant, *The Metaphysics of Morals* (first published 1797), trans and ed M Gregor (1996) 209. See also D Beyleveld and R Brownsword, "Human Dignity, Human Rights and Human Genetics" (1998) 61 *Modern Law Review* 661 at 665-667.

60 Human Genome Organisation, Ethics Committee, Discussion Paper No 1, 1999, *Genome* -

Benefit Sharing (forthcoming), para 6.

61 *Loc cit.*

62 World Health Organisation, Human Genetics Programme, *International Guidelines on Ethical Issues in Medical Genetics and Genetic Services,* 1998.

63 *The Economist,* 14 August 1999, 71.

64 "Iceland's Central Database of Health Records" (1999) 283 *Science* (22 January 1999, 487; M Specter, "Decoding Iceland" *New Yorker,* 18 January 1999, 41. See <<www.stjr.is.htr For recommendations of the HUGO Ethics Committee see **http://www.gene.ucl.ac.uk/hugo/conduct.htm**

65 *The Economist,* 14 August 1999, 71.

66 HUGO Ethics Committee, Discussion Paper, above n 59, par 32.

67 R W Dworkin, *Limits: The Role of Law in Bioethical Decision-making,* 7 (1997). Cited by Smith, *Judicial Decisionmaking* , 99.

68 R Weiss, "Human Cloning Research will be Regulated", *Washington Post,* 20 January 1998 at A1. Bills S368 and HR 922 of the 105 th Congress seek a permanent ban of federal funding for human cloning. But HR 923 seeks to impose an outright ban on human cloning. See Smith, *Judicial Decisionmaking* 115-116.

69 G Gugliotta, "United Against Human Cloning, Hill Leaders Differ on Specifics" *Washington Post,* 4 February 1998, A4.

70 R Weiss, "Panel backs some human clone work", *Washington Post,* 4 June 1997 A1. In 1997, the California State Assembly became the first State in the United States to legislate a prohibition on reproductive cloning of a human being. See *Cal Health and Safety Code* ¶24185 (West 1997). A five year moratorium was imposed on human experimentation in cloning and heavy civil penalties were imposed for violation. Other States have followed.

71 H A Buetow, Book Review, 2 *J Contemporary Health Law and Policy* 173 (1986), noted O'Brien, 181. See generally G P Smith, *Family Values and the New Society: Dilemmas of the 21 st Century* (1998); *Legal and Healthcare Ethics for the Elderly* (1996); *Bioethics and the Law: Medical Socio-Legal and Philosophical Directions for a Brave New World* (1993); *The New Biology Law, Ethics and Biotechnology* (1989); *Final Choices: Autonomy in Health Care Decisions* (1989); *Medical-Legal Aspects of Cryonics: Prospects for Immortality* (1983); *Ethical, Legal and Social Challenges to a Brave New World* (1982); *Genetics, Ethics and the Law* (1981).

72 G Calabrese, Correspondence to Paul D Carrington, 35 *J Legal Education* 23 (1985), noted O'Brien, 166, 182.